UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 24, 2005

MEMORANDUM

Subject: Efficacy Review for Sani-Cloth Plus Germicidal Wipes, EPA Reg. No. 9480-4;
DP Barcode: D315861

From: Nancy Whyte, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510C)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Marshall Swindell PM 33 / Portia Jenkins
Regulatory Management Branch I
Antimicrobials Division (7510C)

Applicant: PDI, The Healthcare Division of Nice-Pak Products, Inc.
Two Nice-Pak Park
Orangeburg, NY 10962

Formulation from the Label:

Active Ingredients)	**% by wt.**
n-Alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chloride……	0.125%
n- Alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chloride	0.125%
Isopropyl alcohol	14.852%
Other ingredients	44.900%
Total	100.00%

I. Background:

The product, Sani-Cloth® Plus Germicidal Wipes (EPA Reg. No. 9480-6) is an Agency registered product developed by PDI, a division of Nice-Pak Products Inc. The product is an impregnated wipe and is registered as a disinfectant (bactericide, virucide, and tuberculocide)

for use on hard, non-porous surfaces of medical institutions in critical care areas, on various types of medical equipment and transportation devices, in patient rooms, child care centers, and in grocery stores and shopping centers. The applicant has submitted an amendment to the registration to add a label claim for the effectiveness of the product against Hepatitis C Virus Efficacy data (MRID No. 465081-01) to support the claim was included in this package. The study was conducted by ATS Labs at 1285 Corporate Center Drive, Suite 110 in Eagan MN 55121.

The data package contained a letter from the applicant to the Agency (dated March 22, 2005), EPA Form 8570-34 (Certification with Respect to Citation of Data), Agency form 8570-35 (Data Matrix), with statements of No Data Confidentiality Claims and Good Laboratory Practice, and the proposed product label (dated March 22, 2005). Also included in the package were a summary of a meeting held with EPA on January 26, 2005 and a letter from Marshall Swindell, PM Team 31. verifying that the expressed liquid from the towelette itself was acceptable for testing, The letter also stated that this method was only to be used until such time as a protocol for testing the towelette itself was approved by the Agency, and posted for use by pesticide producers.

II. Use Directions:

The label indicates that the product may be used on hard, non-porous surfaces including: stainless steel, plastic, Formica®, and glass. The proposed label includes the following directions for disinfection of non-food contact surfaces: Use a wipe to remove heavy soil. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for a full 5 minutes. Use additional wipes if needed to assure continuous five minute wet contact time. Let air dry. For use on external surfaces of ultrasound transducers and probes, the gel on the instruments should be removed with a clean washcloth before using the towelette before using the towelette for disinfection.

III. Agency Standards for the Proposed Change:

Virucides

The effectiveness of virucides must be tested using virological techniques that simulate the conditions under which the product is intended for use. For products with intended use on dry, inanimate environmental surfaces, carrier tests that are variations of either the AOAC Use-Dilution Method (for liquid surface disinfectants) or the AOAC Germicidal Spray Products Test (for surface spray disinfectants) must be used to produce virucidal data. The virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface (petri dish, glass slide, steel cylinder, etc.) for a specified exposure period at room temperature. The virus must be assayed by an appropriate virological technique testing a minimum of four determinations for each dilution. The protocol for the viral assay must include viral recovery, cytotoxicity controls, and ID-50 values. Test results should be reported as the reduction of the virus titer by the activity of the germicide (ID-50 of the virus control less the ID-50 of the test system) expressed as $\log_{10}$ and calculated by a statistical method. For virucidal data to be acceptable, the product must demonstrate complete inactivation

of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. The calculated viral titers must be reported with the test results. Separate studies on two batches of product are required for each virus. These Agency standards are presented in DIS/TSS-7.

Virucides – Novel Virus Protocol Standards

To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory). The validation of a protocol requires the use of a common positive control disinfectant to be tested concurrently with all new products. For the Hepatitis B Virus protocol, the usual control is BTC-835, a quaternary ammonium compound product obtained from Stepan Company. This agent serves as both an intra-laboratory and an inter-laboratory control and is used for analyzing the reproducibility of the efficacy data results for the protocol. These Agency standards are tailored from those presented in the Federal Register, Vol. 65, No. 166, Friday, August 25, 2000.

IV. Summary of Submitted Studies:

1. MRID 465081-01 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Bovine Diarrhea virus as a surrogate for Human Hepatitis C virus" for Sani-Cloth Plus by Karen M. Ramm. Study conducted by ATS Labs. Study completion date: February 12, 2004. Project Number A01896.

This study was conducted against Bovine Viral Diarrhea virus (NADL strain, obtained from ViroMed Laboratories) using bovine turbinate (BT) cells (ATCC CRL-1390, originally obtained from ViroMed Laboratories) as the host system. The product was received ready to use. Horse serum was added to the stock virus culture to obtain a 5% organic soil load. Two lots (Lot Nos. 3B035TUE and 3B030TUE) of the product, Sani-us Cloth Plus, were tested according to ATS Labs protocol number NPP01120803.BVD.1 (copy not provided). Viral films were prepared by spreading 0.2 mL aliquots of the viral inoculum over the bottoms of ten 100 x 15mm sterile glass Petri dishes. Viral films were dried at 20.0°C for 30 minutes at a 43% relative humidity. The films were treated with 2.0 mL of the undiluted express from the towelettes for 2 minutes at 20.0°C. Following exposure, plates were scraped with a cell scraper to resuspend and passed through Sephadex gel columns. Serial dilutions were made in Eagle's minimal essential medium with 2% non-heat inactivated horse serum, 10µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. BT cells were inoculated in quadruplicate with 0.1 mL aliquots of the dilutions and incubated at 36-38°C for 7 days in a humidified atmosphere of 5-7% CO_2. Cultures were then examined for the presence or absence of cytopathic effects, cytotoxicity, and viability. A validation control was performed with Bardac 2280 (50 and 350 ppm concentrations) at a 10 minute contact time at 20.1°C. Controls for cytotoxicity, dried virus count, and neutralization were also performed.

2. "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Confirmatory Assay, Virus: Bovine Diarrhea virus as a surrogate for Human Hepatitis C virus" for Sani-Cloth Plus by Mary J Miller. Study conducted by ATS Labs. Study completion date: January 22, 2004. Project Number A01856. This study was included in MRID No. 465081-01.

This study was conducted against Bovine Viral Diarrhea virus (NADL strain, obtained from ViroMed Laboratories) using bovine turbinate (BT) cells (ATCC CRL-1390, originally obtained from ViroMed Laboratories) as the host system. The product was received ready to use. Horse serum was added to the stock virus culture to obtain a 5% organic soil load. One lot (Lot No. 3B059STY) of the product, Super Sani Cloth, was tested according to ATS Labs protocol number NPP01120203.BVD.2 (copy not provided). Viral films were prepared by spreading 0.2 mL aliquots of the viral inoculum over the bottoms of eight 100 x 15mm sterile glass Petri dishes. Viral films were dried at 20.1°C for 30 minutes at a 48% relative humidity. The films were treated with 2.0 mL of the undiluted express from the towelettes for 2 minutes at 20.1°C. Following exposure, plates were scraped with a cell scraper to resuspend and passed through Sephadex gel columns. Serial dilutions were made in Eagle's minimal essential medium with 2% non-heat inactivated horse serum, 10µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. BT cells were inoculated in quadruplicate with 0.1 mL aliquots of the dilutions and incubated at 36-38°C for 7 days in a humidified atmosphere of 5-7% CO_2. Cultures were then examined for the presence or absence of cytopathic effects, cytotoxicity, and viability. A validation control was performed with Bardac 2280 (50 and 350 ppm concentrations) at a 10 minute contact time at 20.1°C. Controls for cytotoxicity, dried virus count, and neutralization were also performed. All performed as expected.

Results:

Table 1
Effects if Sani-Cloth Plus (Batch #3B035TUE and Batch #3B030TUE)
Following a Two-Minute Exposure to BDVD Dried of an Inaminate Surface

Dilution	Input Virus Control	Dried Virus Control Replicate #1	Dried Virus Control Replicate #2	BVDV + Batch # 3B035TUE Replicate #1	BVDV + Batch # 3B035TUE Replicate #2
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0
10^{-1}	NT	NT	NT	T T T T	T T T T
10^{-2}	NT	NT	NT	0 0 0 0	0 0 0 0
10^{-3}	NT	NT	NT	0 0 0 0	0 0 0 0
10^{-4}	+ + + +	+ + + +	+ + + +	0 0 0 0	0 0 0 0
10^{-5}	+ + + +	+ 0 0 0	0 + 0 0	NT	NT
10^{-6}	0 0 0 0	0 0 0 0	0 0 0 0	NT	NT
10^{-7}	0 0 0 0	0 0 0 0	0 0 0 0	NT	NT
$TCID_{50}$/0.1mL	$10^{5.25}$	$10^{4.75}$	$10^{4.75}$	$\leq 10^{1.25}$	$\leq 10^{1.25}$
MPN	NA	36164	36164	$\leq$23.979	<23.979
Log_{10} MPN	NA	4.55828	4.55828	$\leq$1.37983	$\leq$1.37983
MPN Log Reduction	NA	NA		$\geq$3.18	

V. Recommendations and Comments:

1. The proposed label claims that the product, Sani-Cloth® Germicidal Wipes, is an effective disinfectant with virucidal activity against Hepatitis C virus in the presence of organic soil following exposure for 2 minutes at room temperature. These claims are currently acceptable, as they are supported by the applicant's data.

2. The Agency agreed that it was permissible to test the product using its expressed liquid, and not the complete towelette product until such time as a new wipe protocol was approved for Hepatitis C. This protocol is nearing completion and will soon be posted on the Agency website. When the protocol is posted the applicant is required to submit confirmatory efficacy data for the wipe product following this protocol.